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10/561,271

12/19/2005

Nathalie Piccardi

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FOLEY AND LARDNER LLP  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER

MELLER, MICHAEL V

ART UNIT

PAPER NUMBER

1655

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/561,271 | <b>Applicant(s)</b><br>PICCARDI ET AL. |  |
|                              | <b>Examiner</b><br>Michael V. Meller | <b>Art Unit</b><br>1655                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 20-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 8-16 and 20-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6, 7 and 12-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/19/2005</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group II, claims 6-7, 12-14 in the reply filed on 1/28/2008 is acknowledged. The traversal is on the ground(s) that the extract obtained in JP 08012565 does not comprise peptides derived from hydrophilic proteins. This is not found persuasive because as noted in JP 2003-155213, an aqueous extract of maca is known, see abstract, page 9, first paragraph, where it is shown that maca is contacted with an aqueous solution or in the very least would have been obvious to do so since the aqueous solution on page 9 does come into contact with the maca.
2. Thus, there is no special technical feature, a lack of unity exists, and thus claims 1-5, 8-11, 15, 16, 20-33 are withdrawn by the examiner as being drawn to non-elected inventions.

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Rejections - 35 USC § 112***

- 1.
2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3.

4. Claims 6, 7, 12-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an aqueous peptide extract of maca obtained using a method where the maca is hydrolyzed by an enzyme. Thus, the enzyme is a genus.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the only factor present in the claims is drawn to an aqueous peptide extract of maca obtained using a method where the maca is hydrolyzed by an enzyme. The specification clearly indicates only one preferred embodiment of the invention: using a mixture of amylase and protease to hydrolyze the claimed aqueous peptide extract of maca. The specification fails to describe the structure of even one enzyme other than the amylase/protease mixture. Accordingly, in the absence of sufficient recitation of distinguishing characteristics, the specification

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does not provide adequate written description of the claimed genus (enzyme). Further, it has not been shown on the record that applicant was in possession of any and all enzymatic hydrolyses of maca by showing only the specific amylase/protease mixture. Enzymes differ in both their structures and functions and have specific substrate specificity. Further, as shown by, "Enzymes lock and Key", it is taught that enzymes have a specific "lock and key" analogy. It is stated that enzymes specifically react only with only one or a very few similar compounds, See first page. Thus, the specification by only teaching the amylase/protease mixture as hydrolyzing the maca, does not show possession of using any and all enzymes since enzymes have this very special and unique "lock and key" mechanism which means that not all enzymes will work in applicant's invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of enzyme, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound

itself is required. See *Fiers v. Revel*, 25USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the protease/amylase mixture, but not the full breadth of the claims (any enzyme) meets the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 7, 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 improperly depends from a non-elected claim. Applicant cannot claim what is non-elected.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 6, 12-14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over JP 2003-155213 (already made of record by applicants).

The claims are drawn to an aqueous peptide extract of maca obtained using a method where the maca is hydrolyzed by an enzyme.

JP teaches an aqueous solution is sprayed onto maca powder which would constitute an aqueous maca. Since the aqueous solution contains papain (an enzyme) it would inherently hydrolyze the maca as claimed by applicants. Thus, the claimed subject matter and JP are one and the same. The peptide will also inherently be in the

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extract since maca was hydrolyzed by the papain. The intended use of the maca carries no patentable weight. Water is clearly a cosmetically acceptable excipient.

In the alternative, even if the claimed maca is not identical to the referenced maca with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced maca composition is likely to inherently possess the same characteristics of the claimed maca composition. Thus, the claimed maca composition would have been obvious to those of ordinary skill in the art within the meaning of USC 103. Further, if not anticipated, the result-effective adjustment of particular conventional working conditions is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether the maca of applicant's claims differ and, if so, to what extent, from the maca disclosed by the cited reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Please also note that "the patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or



obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process.” In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983).

9. Claims 6, 7, 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2003-155213 (already made of record by the applicants).

The teachings of JP are above.

JP does not explicitly state how much of the maca is dry matter.

The adjustment of particular conventional working conditions (e.g., determining result effective amounts of the ingredients beneficially taught by the cited references), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, this type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael V. Meller/  
Primary Examiner, Art Unit 1655